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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,153	07/08/2003	Masahide Ohyama	16822	8259

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT PAPER NUMBER

3739

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/615,153	Applicant(s) OHYAMA ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/12/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/8/03</u> . | 6) <input type="checkbox"/> Other: _____  |

***Priority***

Applicant's claim for foreign priority in the instant application is confusing. The Declaration acknowledges the earlier filed applications, but indicates that no priority is claimed. However, the first line of the specification indicates that foreign priority to two earlier Japanese applications is being claimed. No copies of the Japanese applications have been filed. Applicant is required to clarify, and perfect, the claim for priority if applicant intends to claim such priority.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims positively recite the human body, which is non-statutory subject matter. For instance, claim 1 recites "an active electrode which supplies to the body anatomy". There are several other such recitations found throughout the claims. Such recitation should be amended to inferentially recite the body structure, for example "an active electrode adapted to supply the body anatomy with high-frequency current". Such inferential recitation avoids the positive inclusion of tissue (i.e. non-statutory subject matter in the claims).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are unclear with their recitation of non-statutory subject matter. See previous 35 USC 101 rejections.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6-8, 10, 14, 15, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al (5,891,134).

Goble et al disclose an electrosurgical high frequency device that includes an RF generator (14) and active and return electrodes (24,26). Fluid is provided to the balloon to create a conductive path between the electrodes (see Abstract). Sensors are used to detect the current flow between the active and return electrodes to determine impedance, which impedance is used as an indication of the formation of vapor (i.e. bubbles) at the treatment site. Delivery of energy is controlled based on the sensed impedance to either maintain or avoid a vapor pocket (see columns 5 and 6). A controller controls the delivery of energy in accordance with the detected bubbles (i.e. vapor pocket). See column 6, lines 1-5, for example, which indicates the lowering of the energy once the impedance (i.e. bubble formation) has reached a particular level. This

Art Unit: 3739

recitation (i.e. the lowering of the energy upon detection of impedance indicating a vapor state) is deemed to read on applicant's claims 2 and 6-8. The "discharge promoting portion" recited in claim 10 is deemed to correspond to the end of the delivery tube of the Goble et al device which promotes the discharge of fluid to the electrode member.

Claims 1-4, 6-11, 14, 15, 17, 20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al (6,210,405).

The Goble et al ('405) system is substantially analogous to the Goble et al ('134) device and includes active and return electrodes (16,18) disposed in a conductive fluid for the treatment of tissue (see Abstract). Again, Goble et al monitor impedance to determine vaporization of the fluid and control the delivery of RF energy based on impedance (i.e. bubble presence). See columns 9 and 10. Goble et al also teach that the flow rate of the fluid may be controlled in accordance with sensed conditions (col. 8, lines 55+). The electrode may take numerous shapes, including having apertures (Figure 2) or having a spiral shape (Figure 4), which shapes promote the generation of bubbles as fluid flows through the apertures and/or past the spiral.

***Allowable Subject Matter***

Claims 5, 12, 13, 16, 18, 19 and 21 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

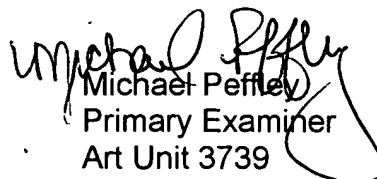
**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Eggers et al (6,066,134) discloses another electrosurgical device that includes a flow of conductive fluid, which fluid may be vaporized to create bubbles at the treatment site. O'Brien et al (2004/0019350) disclose another device providing fluid to electrodes creating bubbles at the treatment site.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael Peffley  
Primary Examiner  
Art Unit 3739

mp  
July 11, 2005